K091134

510(K) SUMMARY

AUG 17 2009

Name of Firm

Custom Spine, Incorporated
1140 Parsippany Blvd, Suite 201
Parsippany, NJ 07054
Phone: (973) 808-0019
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Official Correspondent

Saad Attiyah
Manager of Regulatory Affairs and Quality Assurance
1140 Parsippany Blvd, Suite 201
Parsippany, NJ 07054
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Establishment Number

3005129649

Device Name

Legally Marketed Trade Name: REGENT Anterior Cervical Plate System
Common Name: Spinal Intervertebral Body Fixation Orthosis.
Device Classification: Class II
Regulation Number: 21 CFR 888.3060
Device Product Codes: KWQ

Predicate Devices

X-Spine Anterior Compact Plate System (K041469), Synthes CSLP (K030866)

Device Description

The REGENT Anterior Cervical Plate System is composed of various cervical plates and the screws in made from a Titanium alloy (Ti-6Al-V, ASTM F-136/ISO 5832-3). The REGENT Anterior Cervical System contains multiple level plates (1 Level, 2 Level, 3 Level, and 4 Level) and various diameter screws that are either fixed or variable in nature. The plates and screws are anodized.

Indications for Use

The Regent Anterior Cervical Plate System is intended for anterior cervical plate system is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-**T1**. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)

- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusion
- Spondylolisthesis
- Spinal Stenosis

THIS DEVICE IS ONLY TO BE USED IN SKELETALLY MATURE PATIENTS

WARNING: THIS DEVICE IS NOT INTEDED FOR SCREW ATTACHEMENT OR FIXATION TO THE POSTERIOR ELEMENTS (PEDICLES) OF THE CERVICAL, THORACIC, OR LUMBAR SPINE

Materials

The Regent Anterior Cervical Plate System contains implants are manufactured from Titanium alloy (Ti-6Al-V, ASTM F-136/ISO 5832-3). The system contains instrument and non-implantable devices manufactured from stainless steel.

Performance Data

Performance data per ASTM F 1717-04, " Standard Test Method For Spinal Implant Constructs in a Vertebrectomy Model", were submitted to characterize the subject Regent Anterior Cervical Plate System

Substantial Equivalence Statement

The Custom Spine Regent Anterior Cervical Plate (ACP) System is equivalent to the previously cleared systems, as they utilize the same principle of operation, and has identical indications for use as the predicates, and materials.

Animal Testing

Not Applicable

Bench Testing

The data are included in the submission under "Bench Testing", Section 19.

Clinical Testing

Not Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2009

Custom Spine Inc.
% Mr. Saad Attiyah
Manager of Regulatory Affairs and Quality Assurance
1140 Parsippany Boulevard, Suite 201
Parsippany, New Jersey 07054

Re: K091134
Trade/Device Name: Custom Spine Regent Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 10, 2009
Received: August 10, 2009

Dear Mr. Attiyah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Brennan for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

The REGENT Anterior Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

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THIS DEVICE IS ONLY TO BE USED IN SKELETALLY MATURE PATIENTS.

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Prescription Use __X___ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MXM)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091134